



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/776,044	02/26/1997	MARGARET BYWATER	1614-178P	1463

2292 7590 02/05/2003

BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

[REDACTED] EXAMINER

YU, MISOOK

ART UNIT	PAPER NUMBER
1642	31

DATE MAILED: 02/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)
	08/776,044	BYWATER ET AL.
	Examiner	Art Unit
	MISOOK YU, Ph.D.	1642

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 26 September 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) The period for reply expires 3 months from the mailing date of the final rejection.
- b) The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. A Notice of Appeal was filed on 26 September 2002. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. The proposed amendment(s) will not be entered because:
 - (a) they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) they raise the issue of new matter (see Note below);
 - (c) they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3. Applicant's reply has overcome the following rejection(s): _____.
4. Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. The a) affidavit, b) exhibit, or c) request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. For purposes of Appeal, the proposed amendment(s) a) will not be entered or b) will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 1-10, 14 and 15.

Claim(s) withdrawn from consideration: _____.

8. The proposed drawing correction filed on _____ is a)a) approved or b) disapproved by the Examiner.

9. Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. Other: _____.

SHEELA HUFF
PRIMARY EXAMINER Misook Yu

Continuation of 5. does NOT place the application in condition for allowance because: claim 3 fails to provide enablement because the conclusion step of the claim says that any mutation in the conserved region II and V of p53 is indicative of poor outcome of patient survival whereas any mutation in the conserved region of III and IV is indicative of positive outcome of patient survival. Applicant argues in the amendment (Paper No. 30) that mutation causing a frameshift in amino acid sequence in p53 or nonsense mutation which results in truncated p53 is more detrimental than missense mutation which causes single amino acid substitution. One in ordinary skill would agree with the applicant's argument that out-of frameshift and nonsense mutations are more detrimental to cancer patient because these mutations would knock out the function of affected region of p53. However, the claim say any mutation in conserved region III or V results in better outcome than any mutation in the conserved region of II and V. This is interpreted as a nonsense mutation in the conserved region III results in better outcome than a nonsense mutation in the conserved region V. A nonsense mutation in the conserved region III will abolish the function of the conserved region V because the stop codon is placed well before the region V. Therefore, it is concluded that a mutation in the conserved region III could not result in better outcome than a mutation in conserved region of V. This kind of analysis could also done with out-of frame shift mutation. Any out-of-frame shift mutation in closer to N-terminal p53 is worse than any out-of-frame shift mutation in C-terminal end for the same reason above.

Rejection of claim 15 over Vogelstein et al ('676) is maintained for reason of record. Applicant argues that Vogelstein et al fail to disclose a method for prognostication of the development of neoplasia in a human patient. However, this argument is not persuasive because Vogelstein et al teach at column 1 (see also page 7 Paragraph # 13 of the Office action, Paper No. 25) that the reason for undertaking the study disclosed in the patent is to define the particular genetic region in the short arm of chromosome 17 responsible for progression of curable adenoma to lethal carcinoma. Vogelstein et al teach that that specific genetic region is the gene encoding p53 and mutation in that specific genetic region is responsible for progression of benign, curable disease to lethal carcinoma (indicative of poor patient survival), thus Vogelstein et al teach prognosis of disease for a given patient is poor if a mutation in p53 are found. Claims 1, 2, 4-10, and 14 over Vogelstein et al in view of Elledge et al and Callahan remain rejected for reason of record. Applicant does not argue.